PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference AU04_552	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/AU2004/000552	International filing date *(day/month/year)* 29 April 2004 (29.04.2004)	Priority date *(day/month/year)* 18 February 2004 (18.02.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant PLASMA VENTURES PTY LTD		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 22 August 2006 (22.08.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Dorothée Mülhausen e-mail: pt01@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

Fisher Adams Kelly
GPO Box 1413
BRISBANE QLD 4001

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

	Date of mailing *(day/month/year)* 02 JUL 2004
Applicant's or agent's file reference 12853PC2-DKK/AKB	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/AU2004/000552	29 April 2004	18 February 2004

International Patent Classification (IPC) or both national classification and IPC
Int. Cl. [7] A61D 7/00; A61K 35/16, 39/395, A61M 1/02, 1/38; G01N 33/53

Applicant
PLASMA VENTURES PTY LTD et al

1. This opinion contains indications relating to the following items:

[X]	Box No. I	Basis of the opinion
[ ]	Box No. II	Priority
[ ]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[ ]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[ ]	Box No. VI	Certain documents cited
[ ]	Box No. VII	Certain defects in the international application
[X]	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU	Authorized Officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**TERRY SUMMERS** Telephone No. (02) 6283 3126

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2004/000552

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
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Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	**33-53**	**YES**
	Claims	**1-32, 54-72**	**NO**
Inventive step (IS)	Claims	**33-53**	**YES**
	Claims	**1-32, 54-72**	**NO**
Industrial applicability (IA)	Claims	**1-72**	**YES**
	Claims		**NO**

2. Citations and explanations:

Citations

This opinion has considered the following documents cited in the International Search Report:

D1 Giger U et al,

D2 Hale AS ,

D3 Harvath L et al,

D4 Natanson C et al,

D5 US 4965068 A

D6 Lee R et al,

D1 discloses that mismatching dog erythrocyte antigen 1.1 when transferring blood/plasma between recipient and donor canines results in acute haemolytic transfusion reaction. This document further discloses that when transfusing blood/plasma between recipient and donor canine, the recipient and donor should have compatible dog erythrocyte antigen to prevent haemolytic transfusion reactions (such as the use of a universal donor (DEA 1.1 negative)) . See page 1361 right column paragraph 2.

D2 teaches the Dog Erythrocyte system in canines. This document further teaches that recipient blood/plasma should be typed and cross-matched (such as the use of a universal donor). See page 1328 left column paragraph 1.

D3 discloses the immunisation of canines with P.aeruginosa vaccine via six intramuscular injections at 3-4 day intervals followed by a weekly booster (ie hyperimmunisation) to produce donor plasma containing antibodies against P.aeruginosa. This document further discloses the isolation of said immune plasma from canines, via plasmapheresis, for administration to canine recipients. See page 1152 left column paragraph 2-3.

D4 discloses the isolation of plasma (via femoral arterial catheter) from donor canines infected with a E.coli for administration to canine recipients. See page 244.

D5 discloses hyperimmunoglobulin donor plasma containing antibodies against E.coli J5 and methods of obtaining said plasma. See abstract.

D6 discloses hematopoietic stem cell transplantation using central dual-lumen catheter for apheresis in canines. See abstract, page 338 left column.

Continued in Supplementary Box I

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 55 and dependent claims are not fully supported by the description. There is only support for the isolated canine plasma to be isolated using the method as defined in claim 33. The inventive concept appears to be the production of hyperimmunised plasma for administration to recipient canines wherein the donor canine has a blood group compatible with a recipient canine animal having an unmatched blood group, however as currently drafted the claims are not limited to the inventive concept. For this reason claim 55 and dependent claims is not fully supported by the description.

Supplemental Box I

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of: V

Novelty and Inventive Step

Claim 1-32 encompass a method of isolating plasma from a canine animal including the steps of:

(I) Selecting a donor canine having a blood group compatible with a recipient canine animal having an unmatched blood group;

(II) collecting blood from the canine; and

(III) isolating from blood collected in step (II)

Claim 33-52 encompass a method of producing hyperimmunised canine plasma including the steps of:

(I) Selecting a donor canine having a blood group compatible with a recipient canine animal having an unmatched blood group;

(II) Administering an antigen to canine to induce an immune response;

(III) Administering the same antigen as in (II) during said immune response;

(IV) Isolating plasma from said canine

Claim 53 encompasses isolated canine plasma obtained from a canine hyperimmunised by the method as defined in claims 33-52.

Claim 54 encompasses isolated canine plasma obtained by the method as defined in claims 33-52.

Claim 55-66 encompasses isolated canine plasma comprising at least one immunoglobulin capable of binding to a gram negative bacteria.

Claim 67-72 encompasses the treatment of canine animals by administering isolated canine plasma as defined in claims 53-66.

Method Claims 1-32 and dependent claims (claims 54, 67-72)

The invention defined in claims 1-32, 54, 67-72 is not novel and do not involve an inventive step in light of D1-D2. These documents teach that recipient blood/plasma should be typed and cross-matched (eg by using a universal donor) when isolating/transfusing blood/plasma. For example D1 teaches the use of a universal donor (which is DEA 1.1 negative). Therefore as a method of isolating canine plasma wherein the donor canine has a blood group compatible with a recipient canine animal having an unmatched blood group (ie the use of a universal donor) is known the method defined in claim 1-32 is not novel or inventive. Furthermore as the method is known, claims to isolated plasma by this method (claim 54) and the use of said isolated plasma to administer to recipient canines (claims 67-72) is also not novel and inventive. It is noted the features defined in the dependent claims do not add any features which are considered to be novel or inventive. For these reasons the invention defined in claims 1-32, 54, 67-72 are not novel and do not involve an inventive step in light of D1-D2.

Continued in Supplementary Box II

Supplemental Box II

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of: V

The invention defined in claims 1-32, 54, 67-72 (when appended to claim 54) are novel and inventive in light of D3-D6 as there is no disclosure or suggestion in any of these documents of a method of isolating canine plasma wherein the donor canine has a blood group compatible with a recipient canine animal having an unmatched blood group. In light of D3-D4, even though these citations disclose methods of isolating canine plasma for administration to recipient canines, there is no mention of incompatibility between the donor and recipient canines. Therefore the invention defined in claims 1-32, 54, 67-72 (when appended to claim 54) are novel and inventive in light of D3-D6.

Method Claims 33-52 and dependent claims (claims 53, 67-72)

The invention defined in claims 33-53, 67-72 (when appended to claim 53) are novel and inventive in light of D1-D6. There is no disclosure or suggestion in any of these documents of a method of producing **hyperimmunised** canine plasma wherein the donor canine has a **blood group compatible** with a recipient canine animal having an **unmatched blood group**. Even though D3 discloses a method of isolating hyperimmunised canine plasma for administration to recipient canines, there is no mention of incompatibility between the donor and recipient canines. Therefore even though D1-D2 teach that recipient blood/plasma should be typed and cross-matched (eg by using a universal donor) when isolating/transfusing blood/plasma, as there is no mention of incompatibility between the donor and recipient canines in D3, a person skilled in the art would not be led to utilise a donor canine that has a **blood group compatible** with a recipient canine animal having an **unmatched blood group** to produce hyperimmune canine plasma. Furthermore as the method is novel, claims to isolated plasma by this method (claim 54) and the use of said isolated plasma to administer to recipient canines (claims 67-72) also appear novel and inventive.

Therefore the invention defined in claims 33-53, 67-72 (when appended to claim 53) are novel and inventive in light of D1-D6.

Composition Claims 55-66 and dependent claims (claims 67-72)

The invention defined in claims 55-72 is not novel and do not involve an inventive step in light of D3-D4. These documents disclose isolated canine plasma comprising at least one immunoglobulin capable of binding to a gram negative bacteria (eg P.aeruginosa and E.coli). In light of D4 even though there is no explicit disclosure of immunoglobulins against E.coli, as the canines were infected with E.coli, it would be accepted that the plasma would contain immunoglobulins against said bacteria. For these reasons the invention defined in claims 55-66 are not novel and do not involve an inventive step. Furthermore as said isolated plasma is not novel, the use of said isolated plasma to administer to recipient canines (claims 67-72) is also not novel. It is noted the features defined in the dependent claims do not add any features which are considered to be novel or inventive. For these reasons the invention defined in claims 55-72 is not novel and do not involve an inventive step.

Continued in Supplementary Box III

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International Application No.

PCT/AU2004/000552

Supplemental Box III

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of: V

The invention defined in claims 55-72 are novel in light of D5 as there is no disclosure in any of these documents of isolated **canine plasma** comprising at least one immunoglobulin capable of binding to a gram negative bacteria.

However the invention defined in claims 55-72 do not involve an inventive step in light of D5. D5 discloses hyperimmunoglobulin donor plasma containing antibodies against E.coli J5 and methods of obtaining said plasma. The difference between the D5 and the instant application is that D5 discloses hyperimmunoglobulin donor plasma containing antibodies against E.coli J5 whereas the instant application encompasses isolated **canine** plasma containing antibodies against gram negative bacteria (such as E.coli J5 see claim 57). However this difference does not involve an inventive step as the canine plasma of the instant invention **can be produced using an analogous process to that of D5** with there being no technical difficulties to overcome. For this reason the invention defined in claims 55-66 do not involve an inventive step in light of D5. Furthermore as said isolated plasma does not involve an inventive step, the use of said isolated plasma to administer to recipient canines (claims 67-72) is also not inventive. It is noted the features defined in the dependent claims do not add any features which are considered to be novel or inventive. For these reasons the invention defined in claims 55-72 do not involve an inventive step.

The invention defined in claims 55-66, 67-72 (when appended to claims 55-66) are novel and inventive in light of D1-D2, D6. There is no disclosure or suggestion in any of these documents of isolated **canine plasma** comprising **at least one immunoglobulin** capable of binding to a **gram negative bacteria**.

Industrial Applicability

Claims 1-72 are considered to be Industrial Applicable.